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EXAMINER	
BERTAGNA, ANGELA MARIE	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,471	EBBINGHAUS ET AL.	
	Examiner	Art Unit	
	Angela Bertagna	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 12-18 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 and 19-26 is/are rejected.

7)☒ Claim(s) 2 and 25 is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 August 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/7/04; 11/4/04; 2/9/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 19-26, drawn to methods of identifying a molecule that interacts with quadruplex DNA, identifying a quadruplex structure in a sample, and identifying a nucleotide sequence capable of forming a quadruplex structure, classified in class 435, subclass 6.

II. Claims 12-18, drawn to a method for modulating the biological activity of a biologically significant native quadruplex DNA, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. The methods of Group I are directed toward identification, (specifically the identification of molecules that interact with a native quadruplex DNA, methods of identifying the quadruplex structure, and methods of identifying the nucleotide sequence capable of forming the quadruplex structure). In contrast, the method of Group II is directed to the modulation of the biological activity of a native quadruplex – a fundamentally different process in terms of function and effect than the methods of Group I. The methods of Group I also have a different mode of

operation than the method of Group II. Specifically, the methods of Group I require contacting a test quadruplex DNA with a candidate molecule and screening for interaction, whereas the method of Group II requires contacting a system (a cell or an organism) comprising a native quadruplex DNA with a molecule known to interact with the quadruplex, and thereby modulating the activity of the quadruplex. Therefore, the inventions of Groups I and II are distinct, and restriction is proper.

3. Further Restriction Requirement Applicable to All Groups:

Additionally, each of Groups I and II named above is subject to a further restriction. Applicant is required to further elect one specific sequence for examination.

With regard to the election of a single sequence, different nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claims shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

The search and examination of all possible groups would pose an enormous burden on the examiner and on the PTO search resources. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter due to all of the inventions' different gene sequences would require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore the restriction is deemed proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Specifically, a search for Group I would be focused on the method of identification requiring search terms such as "quadruplex", "interaction", and "candidate molecule", whereas a search for Group II would be focused on modulation of biological activity of a native quadruplex and would require additional search terms not required for a search of Group I, such as "modulate", "biologically significant", "cell", "organism", and "in vivo".

5. During a telephone conversation with Kate Murashige on November 18, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11 and 19-26. In addition, with regard to the additional requirement for restriction, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11 and 19-26 with respect to SEQ ID No. 16. Affirmation of this

election must be made by applicant in replying to this Office action. Claims 12-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Also, claims 1-11 and 19-26 have been examined with respect to the elected SEQ ID No: 16.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claim 2 is objected to because of the following informalities: A period is required at the end of the claim.

Appropriate correction is required.

8. Claim 25 is objected to because of the following informalities: The use of the word "of" in line 3 appears to be grammatically incorrect. It appears that the word "or" was intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3, 4, 7-11, 19, 20, and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Siddiqui-Jain et al. (US Pub No. 2004/0005601 A1). This Pre-grant publication claims priority to Provisional Application No. 60/370,358, filed on April 5, 2002. The citations below refer to the Pre-grant publication.

The applied reference has common inventors (Adam Siddiqui-Jain & Laurence Hurley) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to claim 1, Siddiqui-Jain et al. disclose a method for identifying a molecule that modulates the biological activity of a native quadruplex DNA, which comprises

contacting a test quadruplex DNA with a candidate molecule, wherein the test quadruplex DNA comprises the nucleotide sequence $(GGA)_4$ or the nucleotide sequence $(GGA)_3GG$, and wherein G is guanine and A is adenine (see paragraphs 14 and 32)

determining the presence or absence of an interaction between the candidate molecule and the test quadruplex DNA, whereby the candidate molecule that interacts with the test quadruplex DNA is identified as the molecule that modulates the biological activity of the native quadruplex DNA (see paragraphs 14 and 32).

With regard to claim 3, Siddiqui-Jain et al. disclose that the test quadruplex DNA comprises a nucleotide sequence that is identical to a nucleotide sequence in native quadruplex DNA (paragraph 30).

With regard to claim 4, Siddiqui-Jain et al. disclose that the test quadruplex DNA comprises a nucleotide sequence that is identical to a gene transcription regulatory nucleotide sequence in native quadruplex DNA (paragraph 30).

With regard to claim 7, Siddiqui-Jain et al. disclose that the test quadruplex DNA comprises a mutation that hinders formation of another quadruplex conformation (paragraph 33).

With regard to claim 8, Siddiqui-Jain et al. disclose that the test quadruplex DNA is coupled to a reporter expression system (paragraph 77).

With regard to claim 9, Siddiqui-Jain et al. disclose that the reporter expression system comprises a luciferase reporter (paragraph 77).

With regard to claim 10, Siddiqui-Jain et al. disclose that the interaction is assayed by a Taq polymerase arrest assay (paragraph 76).

With regard to claim 11, Siddiqui-Jain et al. disclose that the interaction is a binding interaction (paragraph 74).

With regard to claim 19, Siddiqui-Jain et al. disclose a method for identifying a quadruplex structure in a nucleic acid of a sample, which comprises contacting the sample with a quadruplex-interacting agent and detecting the presence or absence of an interaction between the nucleic acid and the quadruplex-interacting agent, whereby the presence of an interaction is indicative of the quadruplex structure in the nucleic acid (paragraph 74).

With regard to claim 20, Siddiqui-Jain et al. disclose that the quadruplex-interacting agent is TMPyP4 or telomestatin (Example 4, paragraph 106).

With regard to claim 22, Siddiqui-Jain et al. disclose a method for identifying a nucleotide sequence capable of forming a quadruplex structure, which comprises identifying in a database a subset of nucleotide sequences comprising $(GGA)_4$, $(GGA)_3GG$ or $(GGA)_3GGX_n(GGA)_3GG$, wherein n is an integer between 0 and 3 (paragraph 44). The election of SEQ ID No: 16 in response to the restriction requirement limits the instant claim to "a subset of nucleotide sequences comprising $(GGA)_4$ or $(GGA)_3GG$." Note that the "related sequences that may function as

aptamers" inherently includes nucleotide sequences capable of forming a quadruplex structure.

With regard to claim 23, Siddiqui-Jain et al. disclose that the method of claim 22 further comprises identifying nucleotide sequences from the subset of nucleotide sequences adjacent to a gene coding region (paragraph 44). Note that the test quadruplex sequences used as query sequences are derived from regulatory sequences adjacent to a gene coding region (paragraph 30). Therefore, this disclosure meets the limitations of the instant claim.

With regard to claim 24, Siddiqui-Jain et al. disclose that the method of claim 22 further comprises identifying nucleotide sequences from the subset of nucleotide sequences identical to or substantially identical to an oncogene nucleotide sequence (paragraph 44). Also, note that test quadruplex query sequences are derived from oncogenes (paragraph 30). Therefore, this disclosure meets the limitations of the instant claim.

With regard to claim 25, Siddiqui-Jain et al. disclose a method for identifying a nucleotide sequence capable of forming a quadruplex structure, which comprises:

contacting a cell with a quadruplex interacting agent (Example 4, paragraph 106)

identifying a subset of RNA nucleotide sequences increased or decreased 2-fold or more in the cell as compared to a cell not contacted with the quadruplex interacting agent (Example 4, paragraph 107-108)

identifying a nucleotide sequence from the subset comprising $(GGA)_4$, $(GGA)_3GG$ or $(GGA)_3GGX_n(GGA)_3GG$ as the nucleotide sequence capable of forming a quadruplex structure.

Although Example 4 does not teach "identification of a nucleotide sequence from the subset comprising $(GGA)_4$, $(GGA)_3GG$ or $(GGA)_3GGX_n(GGA)_3GG$ as the nucleotide sequence capable of forming a quadruplex structure", a general method is provided in paragraphs 74 and 88 for contacting cells with a quadruplex interacting agent, measuring the resulting transcriptional levels, and thereby, identifying a nucleotide sequence capable of forming a quadruplex structure. Note that the sequences $(GGA)_4$ and $(GGA)_3GG$ are included in the group of test quadruplexes defined in paragraph 32. Also, the sequence $(GGA)_3GGX_n(GGA)_3GG$ is an unelected sequence, and therefore, was not considered. Therefore, this disclosure of Siddiqui-Jain et al. meets the limitations of the instant claim.

With regard to claim 26, Siddiqui-Jain et al. disclose that the quadruplex interacting agent is TMPyP4 or telomestatin (Example 4, paragraph 106).

Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerwin et al. (US Patent No. 6,156,763).

With regard to claim 19, Kerwin et al. disclose a method for identifying a quadruplex structure in a nucleic acid of a sample, which comprises contacting the sample with a quadruplex-interacting agent and detecting the presence or absence of an interaction between the nucleic acid and the quadruplex-interacting agent, whereby

the presence of an interaction is indicative of the quadruplex structure in the nucleic acid (Example 5, column 23-24). Note that in detecting the photocleavage products resulting from the interaction between the G4A oligonucleotide and the known quadruplex-interacting molecule TMPyP4, Kerwin et al. have inherently identified a quadruplex structure in a nucleic acid of a sample, thus meeting the limitations of the instant claim.

With regard to claim 20, Kerwin et al. disclose that the quadruplex-interacting agent is TMPyP4 or telomestatin (column 23, line 14).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 3, 5-7, 10, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerwin et al. (US Patent No. 6,156,763) in view Matsugami et al. (Journal of Molecular Biology, October 2001).

Kerwin et al. disclose the method of claim 19, as discussed above.

With regard to claim 1, Kerwin et al. disclose a method for identifying a molecule that modulates the biological activity of a native quadruplex DNA, which comprises

contacting a test quadruplex DNA with a candidate molecule (column 2, line 66-column 3, line 2)

determining the presence or absence of an interaction between the candidate molecule and the test quadruplex DNA, whereby the candidate molecule that interacts with the test quadruplex DNA is identified as the molecule that modulates the biological activity of the native quadruplex DNA (column 2, line 66-column 3, line 2).

With regard to claim 1, Kerwin et al. do not disclose that the test quadruplex comprises nucleotide sequence $(GGA)_4$ or the nucleotide sequence $(GGA)_3GG$, and wherein G is guanine and A is adenine.

With regard to claim 3, Kerwin et al. disclose that the test quadruplex DNA comprises a nucleotide sequence that is identical to a nucleotide sequence in native quadruplex DNA (column 10, lines 44-55).

With regard to claim 5 and 21, Kerwin et al. do not teach that the test quadruplex DNA is in a heptad/tetrad conformation.

With regard to claim 6, Kerwin et al. do not teach that the heptad/tetrad conformation is formed by incubation of the DNA in a potassium ion solution for a time period shorter than the time period required to form another quadruplex conformation.

With regard to claim 7, Kerwin et al. teach that the quadruplex comprises a mutation that hinders the formation of another quadruplex conformation (column 28, lines 27-48). Again, Kerwin et al. do not teach that the test quadruplex is in a heptad/tetrad conformation.

With regard to claim 10, Kerwin et al. disclose that the interaction is assayed by a Taq polymerase arrest assay (column 23, Example 4).

With regard to claim 11, Kerwin et al. disclose that the interaction is a binding interaction (column 24, Example 6).

Matsugami et al. teach the structure of a quadruplex of $(GGA)_4$ in a heptad/tetrad conformation (abstract). The sequence was incubated in solutions containing physiological concentrations of potassium ions (100 mM) and in solutions lacking potassium ions and the resulting NMR spectra were compared (Figure 1, page 256).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use the $(GGA)_4$ quadruplex taught by Matsugami et al. in the method of Kerwin et al. in order to increase the number of test quadruplexes, and ultimately, the number of quadruplex-interacting compounds indentified. Matsugami et al. taught that the $(GGA)_4$ sequence forms a quadruplex structure, and in particular, a heptad/tetrad structure, that is likely the biologically relevant conformation (page 265-266). Given that the ordinary practitioner of the method of Kerwin et al. would have

been seeking to identify anticancer and/or anti-telomerase compounds, use of a biologically relevant test quadruplex for screening candidate compounds would have been critical. Furthermore, Matsugami et al. demonstrated the importance of the proper incubation in the potassium ion containing solution (page 255), thereby providing further encouragement for the ordinary artisan to ensure that the potassium ion concentration and time of incubation were optimal for heptad/tetrad formation. Therefore, the ordinary artisan, seeking to identify quadruplex-interacting compounds using the method of Kerwin et al. would have been motivated to conduct the method using the quadruplex formed by the $(GGA)_4$ sequence in a heptad/tetrad conformation properly prepared with respect to potassium ion concentration and incubation time, thus resulting in the instantly claimed method.

14. Claims 5, 6 and 21 are rejected under 35 U.S.C. 103(a) as being obvious over Siddiqui-Jain et al. (US Pub No. 2004/0005601 A1) in view of Matsugami et al. (Journal of Molecular Biology, October 2001).

The applied reference (Siddiqui-Jain et al.) has common inventors (Adam Siddiqui-Jain and Laurence Hurley) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which

corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Siddiqui-Jain et al. disclose the methods of claims 1 and 19, as discussed above.

With regard to claims 5 and 21, Siddiqui-Jain et al. do not teach that the test quadruplex DNA is in a heptad/tetrad conformation.

With regard to claim 6, Siddiqui-Jain et al. do not teach that the heptad/tetrad conformation is formed by incubation of the DNA in a potassium ion solution for a time period shorter than the time period required to form another quadruplex conformation. However, Siddiqui-Jain et al. do teach that variation of the potassium ion concentration and time of exposure to a solution containing potassium ions favors the formation of different quadruplex structures (paragraph 38).

Matsugami et al. teach the structure of a quadruplex of $(GGA)_4$ in a heptad/tetrad conformation (abstract). The sequence was incubated in solutions containing physiological concentrations of potassium ions (100 mM) and in solutions lacking potassium ions and the resulting NMR spectra were compared (Figure 1, page 256).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use the $(GGA)_4$ quadruplex DNA in the heptad/tetrad conformation taught by Matsugami et al. in the methods of Siddiqui-Jain et al., in order to study the native conformation of the $(GGA)_4$ quadruplex. Siddiqui-Jain contemplated using the $(GGA)_4$ sequence as a test quadruplex DNA in the disclosed method of identifying compounds that modulate quadruplex biological activity, as discussed above. Siddiqui-Jain et al. also discussed the importance of conducting the method using the biologically significant form with a more specific discussion related to selecting for the chair rather than the basket conformation of a test quadruplex (paragraphs 38 and 99). Matsugami et al. teach that the heptad/tetrad conformation of the $(GGA)_4$ quadruplex determined by NMR is likely to be the biologically significant form of the quadruplex, and further discuss the importance of using the relevant potassium ion concentration in order to form a complete and stable structure (page 256 and 265-266). The ordinary practitioner of the method of Siddiqui et al. would have been motivated to apply the teachings Matsugami et al. in order to obtain the biologically relevant form of the $(GGA)_4$ quadruplex , and thereby identify more biologically relevant quadruplex-interacting molecules and/or structures. Therefore, the ordinary artisan, interested in obtaining a biologically relevant form of the $(GGA)_4$ quadruplex, would have been motivated to apply the teachings of Matsugami et al. to the method of Siddiqui-Jain et al., thus resulting in the $(GGA)_4$ quadruplex in a heptad/tetrad conformation for use in a method of identifying a quadruplex structure and/or a molecule that modulates the biological activity of a native quadruplex DNA, which is the instantly claimed invention.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 3, and 7-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 7-11 of copending Application No. 10/407,449. Although the conflicting claims are not identical, they are not patentably distinct from each other, because claim 2 of Application No. 10/407,449 recites the limitation that the "test quadruplex DNA comprises a nucleotide sequence selected from the group consisting of $(G_aX_b)_cG_a$, wherein:

G is guanine;

X is guanine, cytosine, adenine or thymine;

a is an integer between 2 to 6;

b is an integer between 1 to 4; and

c is the integer 3." This test quadruplex is to be used in the method of claim 1 which recites "a method for identifying a compound that modulates the biological activity of a native quadruplex DNA, which comprises: (a) contacting the test quadruplex DNA in a chair conformation with a candidate compound and (b) determining the presence or absence of an interaction between the candidate compound and the test quadruplex DNA, whereby the candidate compound that interacts with the test quadruplex DNA is identified as the compound that modulates the activity of the native quadruplex DNA."

The instant SEQ ID No: 2, $(GGA)_3GG$, is a species within the genus $(G_aX_b)_cG_a$ above, and is by definition, capable of being in a chair conformation. Therefore, the instant claim 1 is not patentably distinct over claims 1 and 2 of Application No. 10/407,449. Also, the dependent claims 3 and 8-10 of the instant application are not patentably distinct over claims 4 and 7-9, respectively, of Application No. 10/407,449, because the same limitations are recited, and the species $(GGA)_3GG$ (SEQ ID No: 2) of the instant application is encompassed by the genus $(G_aX_b)_cG_a$ in Application No. 10/407,449. Finally, the instant claim 11 is not patentably distinct over claims 10-11 of Application No. 10/407,449 because as noted above, the species $(GGA)_3GG$ (SEQ ID No: 2) of the instant application is encompassed by the genus $(G_aX_b)_cG_a$, and further, claims 10 and 11 recite that the interaction is a binding interaction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

17. The following is a statement of reasons for the indication of allowable subject matter: Claim 2, which recites "the method of claim 1, wherein the test quadruplex DNA comprises a nucleotide sequence selected from the group consisting of SEQ ID No: 16", contains allowable subject matter. The restriction requirement above limits claim 2 to SEQ ID No: 16. A nucleotide sequence search retrieved nucleic acid sequences comprising the instant SEQ ID No: 16 (for example, Bullerdiek et al., US Patent No. 6,544,784; Young, US Pub No. 20020115057A1; Dale et al. US Pub No. 20030207834A1). However, these references teach gene sequences of approximately 4000 bp and neither teach nor suggest the use of the 38 bp region comprising the instant SEQ ID No: 16 contained within said genes in a method of identifying quadruplex-interacting molecules or quadruplex-forming structures. The regions of these prior art sequences corresponding to the instant SEQ ID No: 16 were not identified by the prior art as being capable of forming quadruplex structures. Therefore, if claim 2 was amended to cancel the non-elected sequences, this claim would be allowable. Also, amendment of claims 1, 22, and 25 to replace SEQ ID Nos: 1-6 with SEQ ID No: 16 would render claims 1, 3-11 and 22-26 free of the prior art.

Conclusion

18. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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